

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:

Hornack, Janmarie et al.

Serial No.:

Filed:

Title: DIETARY SUPPLEMENT
CONTAINING ALKALINE
ELECTROLYTE BUFFERS

Date: July 22, 2003

Group Art Unit:

Examiner:

Box Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

LETTER

Background

This continuation application is filed as a replacement for Serial No. 09/706,005, which was finally rejected in an Office Action of April 22, 2003. The claims of record in this continuation application are the claims that were finally rejected by the Examiner in the April 22, 2003 Office Action, except that claim 1 substituted for original claim 21 has been amended to delete reference to enzymes, amino acids and medicaments as being exemplary therapeutic supplement agents. For clarity the term "plant" has been added before the recitation of "food products" in the first paragraph of claim 1.

By filing this continuation application as a substitute for parent application Serial No. 09/706,005 and which contains the claims finally rejected in the April 22, 2003 Office Action in the parent case, applicant seeks reconsideration of the rejection of the claims as being unpatentable under 35 U.S.C. § 103(a) based on Kirschner U.S. Patent No. 6,261,600, the sole reference relied upon by the Examiner in finally rejecting claims 3, 7, 9-13, 16 and 21 in the '005 application.

Of these remaining claims, claims 9-13 and 16 were objected to in the April 22, 2003 Office Action in the '005 application as being dependent from rejected claims. Otherwise, claims 9-13 and 16 were deemed allowable.

The '005 application as filed November 3, 2000 contained 20 claims. Claims 1-16 were rejected in an Office Action of May 7, 2001 as being indefinite under 35 U.S.C. § 112, while claims 1-16 were rejected as being unpatentable over four cited references, Hornack, Herschler, Demopoulos and Roser. Method claims 17-20 were subject to a restriction objection and applicant elected claims 1-16 for further prosecution. In applicant's response of November 13, 2001 to that Office Action, accompanied by a Request for Revival after inadvertent abandonment of the application, claims 1 and 16 were amended and an argument presented as to why the claims were patentable over the references cited by the Examiner. The Petition for Revival was granted on January 14, 2002.

The Examiner then issued an Office Action dated April 9, 2002, in which the remaining claims were finally rejected based on Herschler, Walsh, Demopoulos, New et al. and Chen. Applicant filed a Notice of Appeal on August 6, 2002 from the Examiner's April 9, 2002 final rejection. A further response was filed on October 3, 2002, subsequent to the Notice of Appeal, in which claims 1 and 4 were cancelled, and new claim 21 was substituted for original claim 1. The Examiner issued an Advisory Action on December 17, 2002, stating that the October 3, 2002 reply failed to place the application in condition for allowance. Claims 21, 3 and 7 were rejected on the art as being unpatentable over the newly cited Kirschner '600 patent, which issued July 17, 2001, subsequent to applicant's filing date of November 3, 2000.

Applicant answered the December 17, 2002 Office Action in a response dated January 22, 2003, in which a Rule 131 Declaration and exhibit was submitted swearing back of the issue date of the Kirschner '600 patent. The Examiner issued a Final Rejection on April 22, 2003, holding that the Rule 131 Declaration was inadequate to swear back of Kirschner based on the assertion that the evidence presented was not commensurate with the scope of the claimed subject matter.

Request for Reconsideration

A. Claims Finally Rejected in Parent Application.

Claim 21 is directed to an improved dietary and/or therapeutic supplement composition consisting of agents selected from the group consisting of vitamins, bioflavonoids, minerals, trace minerals, food products containing phytonutrients, and herbs and each having a pH of 6 or less which upon ingesting with food or a beverage would limit the availability of the agent in the

stomach of a person ingesting the agent. An electrolyte additive selected from the group consisting of calcium, magnesium and potassium electrolytes is incorporated with the agent, with a sufficient amount fo the electrolyte additive being provided in combination with the agent to raise the pH of the combination to a pH of from about 8 to about 12.5. As a result, the alkaline pH of the supplement composition is maintained in the person's stomach upon ingestion of the composition with food or a beverage and during digestion thereof in the person's stomach thereby increasing the effectiveness and utilization of the agent in the person's body.

B. The Kirschner '600 Patent.

The Kirschner '600 patent issued July 17, 2001 subsequent to filing date of applicant's '005 parent application, which was filed November 3, 2000. The Kirschner patent relates to a folic acid supplement. The patentee adds a neutralizing alkaline compound to a folic acid compound in a chewable or dissolvable form. The chewing or dissolving action of the folic acid is said to activate a neutralizing agent in the person's mouth thereby creating an acid neutralizing environment for the folic acid which continues as the composition moves through the stomach into the intestinal track where the folic acid is absorbed into the person's body.

Kirschner do not state that a sufficient amount of the acid neutralizing alkaline compound is provided to maintain the pH of the folic acid composition at a pH of about 8 to about 12.5 in the person's stomach.

C. The Final Rejection.

1. The rejection of claim 21 on Kirschner et al. was repeated with the acknowledgment that although Kirschner et al. did not teach the specific pH range recited in claim 21, one of ordinary skill in the art would have been motivated by Kirschner et al. to increase the pH of the vitamin supplement with a "reasonable expectation for increasing the effectiveness of the supplement, since such alkaline environments are specifically taught to do so." (Office Action, 04/22/2003, pg. 4)

2. Applicant's Rule 131 Declaration filed in the '005 parent application was dismissed by the Examiner as not being persuasive because "the evidence [submitted] is not commensurate with the scope of the claim." (Office Action, 04/22/2003, pg. 4) It was the Examiner's position that applicant's disclosure of seven agents combined with one or more of three electrolytes and said to be limited to specific volumes, was not commensurate with the

scope of the claims because there are “innumerable agents that fall into the categories of therapeutic or dietary agents that are known to promote health”. (Office Action, 04/22/2003, pg.4)

D. Controlling Law.

The purpose of a Rule 131 affidavit is not to demonstrate prior invention *per se*, but merely to antedate the effective date of a reference. *In re Eickmeyer*, 602 F.2d 974, 978 (CCPA 1979) In *In re Stempel, Jr.*, 241 F.2d 755, (CCPA 1957), the Court held that all an applicant is required to show is “priority with respect to so much as the claimed invention as a reference happens to show. When he has done that he has disposed of the reference.” Thus, evidence of prior invention of a species within a claim disposes of that reference as to the genus of which the species is a member.

The overarching principle of *Stempel* was reaffirmed in *In re Tanczyn*, 347 F.2d 830, 833 (CCPA 1965), where the Court refused to sanction a broad rule based on an interpretation of *Stempel* that an entire claimed invention must be shown in the Rule 131 affidavit evidence to overcome a reference except in all cases other than the genus-species situation. The Court in *Tanczyn* said “[t]he primary consideration is whether, in addition to showing what the reference shows, the affidavit also establishes possession of either the whole invention claimed *or something falling within the claim*, in the sense that the claim as a whole reads on it.”

In *In re Spiller*, 500 F.2d 1170, 1177-78 (CCPA 1974), the Court held that “appellant’s should not be required to submit facts under Rule 131 showing that they reduced to practice that which is obvious in addition to those facts offered as showing a completion of the invention, for the purposes of antedating a reference. . . . under Rule 131, it is sufficient that appellant has shown a reduction to practice of his basic invention, which showing will also suffice as to claims differing therefrom only in details which are obvious to one of ordinary skill in the art.”

FN. 5. Since the purpose of the Rule 131 showing is to establish broadly possession of the invention, *In re Tanczyn*, it is proper to consider the obviousness of the differences between what is shown and what is claimed because possession of what is shown carries with it possession of variations and adaptations which would, at the same time be obvious to one skilled in the art.

Spiller, at 1178.

E. Third Party Declarations.

Attached to this letter as Exhibits A - D inclusive are declarations of individuals skilled in the relevant art as represented by their education and experience, each stating in their opinion the improved results obtained from applicant's invention as set forth in the attachment to the Hornack 131 Declaration would extend to obvious variations and adaptations of the specific dietary and/or therapeutic supplement agents recorded by applicant in Exhibit B of her declaration. (Hornack Declaration, Par. 7, a copy of which is attached as Exhibit E)

The third party declarations include statements by bionutrition expert Robert Carr, President of Biokinetic Research, Inc. (Exhibit A), Dr. Peipei Wu Wishnow, President and founder of Interceuticals, Inc. (Exhibit B), Dr. Robert Berger, cofounder of KB-Research Group which develops and markets nutraceuticals (Exhibit C), and Michael Kessler, owner and operator of Kessler & Associates, LLC, a market-consulting firm having a compliment of clinical research and development and other entities relating to the nutraceutical field (Exhibit D).

F. Argument.

The Examiner in the April 22, 2003 final rejection of claim 21 in the '005 parent application (now claim 1 in amended form) asserted that the Hornack Rule 131 affidavit submitted in the '005 application was unpersuasive because the Hornack declaration was not commensurate in scope with the claims.

The attachment B to the Hornack declaration shows that at least as early as July 23, 1998, applicant had added sufficient magnesium, calcium and potassium electrolytes to a vitamin E product (mixed tocopherols 10 IU) to raise the pH of the composition to 8.02. Specifically, Ms. Hornack added 30 mg of calcium carbonate, 30 mg of magnesium carbonate and 150 mg of potassium carbonate to mixed tocopherols having a pH of about 3.2 to increase the pH of the composition to 8.02.

It is therefore clear that the documentary evidence submitted with the Hornack Rule 131 declaration is a showing of what the Kirschner et al. reference shows, i.e., applicant's combination of a sufficient amount of an electrolyte with an acidic vitamin (mixed tocopherols [vitamin E]) to bring the pH to 8+ versus the Kirschner et al. combination of a chewable or dissolvable alkaline composition with folic acid (an acidic vitamin).

The Hornack 131 declaration establishes possession of “*something* falling within the claim, [now claim 1 of this application] in the sense that the claim as a whole reads on it”, at a date prior to the issuance date of the Kirschner et al. ’600 patent. *In re Tanczyn* at 833. (emphasis added) Under prevailing legal authority, it is not necessary that applicant show that everything that would come within the claim was done prior to the issuance date of a cited reference.

The Carr, Wishnow, Berger and Kessler declarations (all artisans skilled in this art) verify that it would be obvious to those skilled in this art, from a review of the Hornack notebook entry, Exhibit B to the Hornack declaration, that the same improved bioavailability resulting from the combination of a sufficient amount of an electrolyte with an acidic vitamin to bring the pH of a level from about 8 to about 12.5, would be obtained with obvious variations and adaptations of the specific supplement agents such as acidic water soluble vitamins, bioflavonoids, minerals, phytonutrients and herbs as recited in claim 1 of this application.

The Examiner asserted in the final rejection that at the time of applicant’s invention (at least as early as July 1998) it would have been well within the purview of one of ordinary skill of the art to increase the pH of a vitamin supplement by addition of electrolytes in order to increase the effectiveness of the composition, with a reasonable expectation for increasing the effectiveness of the supplement, since such alkaline environments are specifically taught to do so.

Section 715.02 MPEP states:

where the differences between the claimed invention and the disclosure of the reference(s) are so small as to render the claims obvious over the reference(s), an affidavit or declaration under 37 CFR 1.131 is required to show *no more* than the reference shows. *In re Stryker*, 435 F.2d 1340, (CCPA 1971) (emphasis added).

The Examiner in the final rejection of April 22, 2003, asserted that any differences between the subject matter of what was claim 21 and is now claim 1 in this continuation application would have been obvious to one skilled in the relevant art.

Applicant submits with this letter substantial evidence in the form of four separate affidavits from skilled artisans in this field that the differences between the specific disclosure of the Kirschner et al. ’600 patent and parent claim 1 of this application would have been obvious to one of ordinary skill in the art. Section 715.02 MPEP states explicitly:

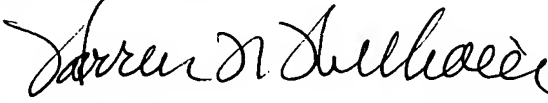
Even if applicant's 37 CFR 1.131 affidavit is not fully commensurate with the rejected claim, the applicant can still overcome the rejection by showing that the differences between the claimed invention and the showing under 37 CFR 1.131 would have been obvious to one of ordinary skill in the art, in view of applicant's 37 CFR 1.131 evidence, prior to the effective date of the reference(s) or the activity. Such evidence is sufficient because applicant's possession of what is shown carries with it possession of variations and adaptations which would have been obvious, at the same time, to one of ordinary skill in the art.

The Hornack declaration submitted in the '005 parent application factually and legally swears back of the Kirschner et al. '600 patent and removes that patent as an effective reference against the claims in this continuation application that were previously rejected based on the disclosure of the '600 patent.

Applicant continues to reserve the right to file a divisional application on the method claims that were the subject matter of a restriction requirement in the '005 parent application. It is submitted that claims 1-9 should be found allowable when this application is reached for attention.

Respectfully submitted,

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(Docket No. 30900-CNT)